

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Carlo M. Croce and George A. Calin  
Application No.: 10/530,792 Group Art Unit: 1734  
371(c) Date: May 13, 2005 Examiner: Not yet assigned  
Confirmation No.: 2613  
Title: NOVEL TUMOR SUPPRESSOR GENE AND COMPOSITIONS  
AND METHODS FOR MAKING AND USING THE SAME

CERTIFICATE OF MAILING OR TRANSMISSION	
I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, or is being facsimile transmitted to the United States Patent and Trademark Office on:	
<u>10/6/2005</u>	<u>Denise Canedo</u>
Date	Signature
<u>Denise Canedo</u>	
Typed or printed name of person signing certificate	

INFORMATION DISCLOSURE STATEMENT

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

This Information Disclosure Statement is submitted:

- ☐ under 37 CFR 1.129(a), or  
(First/Second submission after Final Rejection)
- ☒ under 37 CFR 1.97(b), or  
(Within any one of the following time periods: three months of filing national application (other than a CPA) or date of entry of the national stage in an international application; or before the mailing date of a first office action on the merits in a non-provisional application, including a CPA, or a Request for Continued Examination).
- ☐ under 37 CFR 1.97(c) together with either:
- ☐ a Statement under 37 CFR 1.97(e), as checked below, or
- ☐ a \$180.00 fee under 37 CFR 1.17(p), or  
(After the 37 CFR 1.97(b) time period, but before final action or notice of allowance, whichever occurs first)
- ☐ under 37 CFR 1.97(d) together with:
- ☐ a Statement under 37 CFR 1.97(e), as checked below, and
- ☐ a \$180.00 fee under 37 CFR 1.17(p), or  
(Filed after final action or notice of allowance, whichever occurs first, but on or before payment of the issue fee)
- ☐ under 37 CFR 1.97(i):  
Applicant requests that the IDS and cited reference(s) be placed in the application file.  
(Filed after payment of issue fee)

Statement Under 37 CFR 1.97(e)

- ☐ Each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement; or
- ☐ No item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned, after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of this Information Disclosure Statement.

Statement Under 37 CFR 1.704(d) (Patent Term Adjustment)

Applies to original applications (other than design) filed on or after May 29, 2000

- ☐ Each item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart application and this communication was not received by any individual designated in § 1.56(c) more than thirty days prior to the filing of the Information Disclosure Statement.
- ☒ Enclosed herewith is form PTO-1449:
  - ☒ Copies of the cited references, C1-C13, are enclosed.
  - ☒ Copies of issued U.S. patents and published U.S. applications are not required and are not being provided.
  - ☐ Copies of the cited references are enclosed except those entered in prior application, U.S. Application No. [ ], to which priority under 35 U.S.C. 120 is claimed. [The earlier application contains copies of the cited references.]
  - ☐ The listed references were cited in the enclosed International Search Report in a counterpart foreign application.
  - ☐ The "concise explanation" requirement (non-English references) for reference(s) [ ] under 37 CFR 1.98(a)(3) is satisfied by:
    - ☐ the explanation provided on the attached sheet.
    - ☐ the explanation provided in the Specification.
    - ☐ submission of the enclosed International Search Report.
    - ☐ submission of the enclosed English-language version of a foreign Search Report and/or foreign Office Action.
    - ☐ the enclosed English language abstract.

☒ Applicant requests that the following non-published pending application be considered:

Examiner's  
Initials

\_\_\_\_ U.S. Patent Application No. 11/093,746, by Carlo M. Croce and George A. Calin, filed March 30, 2005, Attorney Docket No.: 3589.1015-003.

\_\_\_\_ U.S. Patent Application No. [ ], by [inventor(s)], filed [ ], Docket No.: [ ]

\_\_\_\_ U.S. Patent Application No. [ ], by [inventor(s)], filed [ ], Docket No.: [ ]

\_\_\_\_\_  
Examiner

\_\_\_\_\_  
Date

☒ A copy of each above-cited application, including the current claims, is enclosed, except any application filed on or after June 30, 2003, which has been scanned into the PTO's Image File Wrapper (IFW) system and is available to the examiner.

☐ A copy of each above-cited application, including the current claims, is enclosed, except those entered in prior application, U.S. Application No. [ ], to which priority under 35 U.S.C. 120 is claimed.

The Examiner is requested to return a copy of the above list of pending applications indicating which references were considered with the next office communication.

It is requested that the information disclosed herein be made of record in this application.

Method of payment:

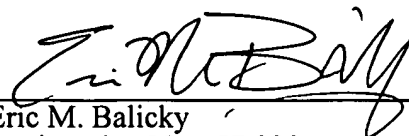
☐ A check for the fee noted above is enclosed, or the fee has been included in the check with the accompanying Reply. A copy of this Statement is enclosed.

☐ Please charge Deposit Account 08-0380 in the amount of \$[ ]. A copy of this Statement is enclosed.

☒ Please charge any deficiency in fees and credit any overpayment to Deposit Account 08-0380.

Respectfully submitted,

HAMILTON, BROOK, SMITH & REYNOLDS, P.C.

By 

Eric M. Balicky  
Registration No.: 57,020  
Telephone: (978) 341-0036  
Facsimile: (978) 341-0136

Concord, MA 01742-9133

Dated: *October 6, 2005*

PTO-1449 REPRODUCED		ATTORNEY DOCKET NO. 3589.1015-008		APPLICATION NO. 10/530,792	
<b>INFORMATION DISCLOSURE STATEMENT IN AN APPLICATION</b>  <b>September 27, 2005</b> (Use several sheets if necessary)		FIRST NAMED INVENTOR Carlo M. Croce		371(C) DATE May 13, 2005	
		EXAMINER Not yet assigned		CONFIRMATION NO. 2613	
				GROUP 1734	

## U.S. PATENT DOCUMENTS

EXAM- INER INI- TIAL	REF. NO.	DOCUMENT NUMBER Number-Kind Code (if known)	ISSUE DATE / PUBLICATION DATE MM-DD-YYYY	NAME OF PATENTEE OR APPLICANT OF CITED DOCUMENT
	A1	6,531,456 B1	03-11-2003	Kurtzman, <i>et al.</i>

## FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER Country Code-Number-Kind Code (if known)	DATE MM-DD-YYYY	NAME OF PATENTEE OR APPLICANT OF CITED DOCUMENT	TRANSLATION YES NO	
	B1					
	B2					

EXAMINER	DATE CONSIDERED
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	EXAMINER Not yet assigned	CONFIRMATION NO. 2613	GROUP 1734	

**OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)**

C1	GenBank Acc. No. AF441378 "Homo sapiens ADP-ribosylation Factor-like Tumor Suppressor Protein 1 (ARLTS1) mRNA, Complete cds," (2003), [online][retrieved on 9/16/2005].
C2	GenPept Acc. No. AAH13150 "ADP-ribosylation Factor-like 11 [Homo sapiens]," (2004), [online] [retrieved on 9/16/2005].
C3	Bullrich, F., and Croce, C. M., "Molecular Biology of Chronic Lymphocytic Leukemia," In Chronic Lymphoid Leukemias: Second Edition, Revised and Expanded (ed. Cheson, B.D.) pp. 9-32 (Marcel Dekker, Inc., New York, Basel, 2001).
C4	Brown, A. G., <i>et al.</i> , "Evidence for a New Tumour Suppressor Locus ( <i>DBM</i> ) in Human B-cell Neoplasia Telomeric to the Retinoblastoma Gene," <i>Nat. Genet.</i> , 3(1):67-72 (1993).
C5	Hawthorn, L. A., <i>et al.</i> , "The Consistent 13q14 Translocation Breakpoint Seen in Chronic B-cell Leukaemia (BCLL) Involves Deletion of the D13S25 Locus Which Lies Distal to the Retinoblastoma Predisposition Gene," <i>Oncogene</i> , 8(6):1415-1419 (1993).
C6	Liu, Y., <i>et al.</i> , "Chronic Lymphocytic Leukemia Cells with Allelic Deletions at 13q14 Commonly Have One Intact <i>RB1</i> Gene: Evidence for a Role of an Adjacent Locus," <i>Proc. Natl. Acad. Sci. USA</i> , 90: 8697-8701 (1993).
C7	Weinberg, R. A., "Tumor Suppressor Genes," <i>Science</i> , 254(5035):1138-1146 (1991).
C8	Moss, J., and Vaughan, M., "Molecules in the ARF Orbit," <i>J. Biol. Chem.</i> , 273(34):21431-21434 (1998).
C9	Kahn, R. A., <i>et al.</i> , "The ras Superfamily of GTP-binding Proteins: Guidelines on Nomenclature," <i>FASEB J.</i> , 6:2512-2513 (1992).
C10	Jacobs, S., <i>et al.</i> , "ADP-Ribosylation Factor (ARF)-like 4, 6, and 7 Represent a Subgroup of the ARF Family Characterized by Rapid Nucleotide Exchange and a Nuclear Localization Signal," <i>FEBS Lett.</i> , 456(3):384-388 (1999).
C11	Kuramochi, M., <i>et al.</i> , " <i>TSLC1</i> is a Tumor-suppressor Gene in Human Non-small-cell Lung Cancer," <i>Nat. Genet.</i> , 27(4):427-430 (2001).
C12	Merlo, A., <i>et al.</i> , "5' CpG Island Methylation is Associated with Transcriptional Silencing of the Tumour Suppressor <i>p16/CDKN2/MTS1</i> in Human Cancers," <i>Nat. Med.</i> , 1(7):686-692 (1995).

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	FIRST NAMED INVENTOR <b>Carlo M. Croce</b>		371(C) DATE <b>May 13, 2005</b>	
	EXAMINER <b>Not yet assigned</b>	CONFIRMATION NO. <b>2613</b>	GROUP <b>1734</b>	

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)		
	C13	Jones, P. A., and Laird, P. W., "Cancer Epigenetics Comes of Age," <i>Nature Genet.</i> , 21:163-167 (1999).

EXAMINER	DATE CONSIDERED
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